Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 33-44 are pending in the application, with 33 being the independent claim. Support for the amendment to claims 33, 34, 40, 41, and 44 is found in the claims as originally filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 40 and 41 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, page 2). Applicants respectfully traverse this rejection.

The Examiner alleges that claims 40 and 41 are indefinite because they list phentolamine mesylate as an alpha adrenergic receptor antagonist but are dependent from claim 33 which refers to phentolamine mesylate or another alpha adrenergic receptor antagonist. (Office Action, page 2).

Applicants respectfully disagree. Claim 40 as amended does not refer to phentolamine mesylate. Claim 41 as amended is dependent from claim 33 and refers to phentolamine mesylate in appropriate fashion.

It is respectfully requested that the rejection of claims 40 and 41 under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 33-36 and 38-41 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Scott (U.S. Patent No. 6,291,528). (Office Action, page 3). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Scott "anticipates the claimed invention (see, e.g. column 12 lines 33-38 and column 12 lines 39-42) because Scott teaches a composition comprising .25mg phentolamine mesylate and a pharmaceutically acceptable carrier and the claimed application." (Office Action, page 2).

Applicants respectfully disagree. The claims as amended are directed to a unit dose of a composition consisting essentially of phentolamine mesylate or another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier. The term "consisting essentially of" indicates that the only active ingredient in the unit dose is the phentolamine mesylate or another alpha adrenergic receptor antagonist.

In contrast, Scott teaches that the addition of phentolamine mesylate increases the beneficial characteristics of PGE_2, and the compositions taught by Scott comprise PGE_2, $PGF_{2\alpha}$, and phentolamine mesylate (column 12, lines 13-37). Since Scott does not teach a unit dose of a composition having phentolamine mesylate as the only active ingredient, Scott cannot anticipate the present claims.

It is respectfully requested that the rejection of claims 33-36 and 38-41 under 35 U.S.C. § 102(e) be withdrawn.

Claims 33-35, 40, and 41 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Helmy (U.S. Patent No. 5,370,613). (Office Action, page 3). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Helmy "anticipates the claimed invention (see, e.g. column 4 lines 49-55) because Helmy teaches a composition comprising .25mg phentolamine mesylate and a pharmaceutically acceptable carrier and the claimed application (i.e. by injection)." (Office Action, page 3).

Applicants respectfully disagree. The claims as amended are directed to a unit dose of a composition consisting essentially of phentolamine mesylate or another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier. The term "consisting essentially of" indicates that the only active ingredient in the unit dose is the phentolamine mesylate or another alpha adrenergic receptor antagonist.

In contrast, Helmy teaches compositions comprising papaverine HCl and phentolamine mesylate (column 4, lines 51-56). Since Helmy does not teach a unit dose of a composition having phentolamine mesylate as the only active ingredient, Helmy cannot anticipate the present claims.

It is respectfully requested that the rejection of claims 33-35, 40, and 41 under 35 U.S.C. § 102(b) be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 33-44 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Scott (U.S. Patent No. 6,291,528). (Office Action, page 4). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that:

> Scott does not expressly teach the composition is a solution is used to impregnate and the unit dosage of the solution is present in a container that fits into a standard dental local anesthetic syringe. However, based upon the overall beneficial teachings provided by Scott, the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one type of administration for another, the solution is used to impregnant and the form of the solution being placed in a container first than into a syringe), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skill artisan.

(Office Action, pages 4-5). Applicants respectfully disagree.

As discussed above, Scott does not disclose a unit dose of a composition consisting essentially of phentolamine mesylate as the only active ingredient. There is no motivation provided in Scott to alter the composition comprising PGE_2, $PGF_{2\alpha}$, and phentolamine mesylate to a composition containing only phentolamine mesylate for use in the treatment of erectile dysfunction because Scott teaches that PGE_2 is the main active ingredient and that phentolamine mesylate is included only because it increases the beneficial characteristics of PGE_2 (column 2, lines 54-59; column 12, lines 13-27). There is no suggestion in Scott that phentolamine mesylate alone is effective for treatment of erectile dysfunction. Thus, one of ordinary skill in the art reading Scott would not prepare a unit dose of a composition consisting essentially of phentolamine mesylate as the only active ingredient for the treatment of erectile dysfunction.

It is respectfully requested that the rejection of claims 33-44 under 35 U.S.C. § 103(a) be withdrawn.

Claims 33-44 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Helmy (U.S. Patent No. 5,370,613). (Office Action, page 5). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that:

> Helmy does not expressly teach the composition is a solution is used to impregnate, all the different types of administration and the unit dosage of the solution is present in a container that fits into a standard dental local anesthetic syringe. However, based upon the overall beneficial teachings provided by Helmy, the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one type of administration for another, the solution is used to impregnate and the form of the solution being placed in a container first than into a syringe), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skill artisan.

(Office Action, page 5). Applicants respectfully disagree.

As discussed above, Helmy does not disclose a unit dose of a composition consisting essentially of phentolamine mesylate as the only active ingredient. There is no motivation provided in Helmy to alter the composition comprising papaverine HCl and phentolamine mesylate to a composition containing only phentolamine mesylate for use in the treatment of erectile dysfunction because Helmy's only teaching of drugs useful for the treatment of erectile dysfunction is the combination of papaverine HCl and phentolamine mesylate in a 30:1 ratio by weight (column 12, lines 51-56). There is no suggestion in Helmy that phentolamine mesylate alone is effective for treatment of erectile dysfunction. Thus, one of ordinary skill in the art reading Helmy would not prepare a unit dose of a composition consisting essentially of phentolamine mesylate as the only active ingredient for the treatment of erectile dysfunction.

It is respectfully requested that the rejection of claims 33-44 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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